

## REMARKS

The remainder of this amendment is set forth under appropriate subheadings for the convenience of the Examiner.

Amendment of Claim 1

Claim 1 has been amended to include the additional limitation that the inner shaft is slideably disposed along a major axis of the inner shaft within the outer sleeve, whereby actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant. Support for this amendment can be found at page 7, lines 18 through 20, in conjunction with the embodiment of the elected species represented by Figure 2A. As stated at page 7, and with reference to Figure 2A, “when trigger mechanism 120 is ‘squeezed’ toward handle 112, grabber 160 (Figure 2A-2C) extends from actuator assembly 126 and expands to release or attach to an implant.” As a further explanation of support for the amendment to claim 1, page 7, lines 1 through 6, states that grabber 160, when assembled, is attached to inner shaft 140 at threaded end 144, and outer sleeve 130 of the actuator assembly 126 includes a tapered end 175 which slidably engages tapers 163 on grabber 160, as shown in Figure 2A:

Actuator assembly 126 includes outer sleeve 130, inner shaft 140, and retaining pin 148. Outer sleeve 130 includes a tapered end 175 which slidably engages tapers 163 on grabber 160 (Figure 2A-2C), allowing for compression and expansion of the grabber 160 when in use. Inner shaft 140 includes female threaded end 142 and male threaded end 144. Female threaded 142 mates with spring retaining screw 152 and male threaded end 144 mates with grabber 160.

As stated at page 6, lines 27, 28, “insertion instrument 100 is a normally closed device, that is, grabber 160 is normally substantially contained within actuator assembly 126.” Therefore, amendment of claim 1 to include the limitation that an inner shaft is slidably disposed along its major axis within an outer sleeve, and that actuation of a trigger extends a grabber from the outer sleeve to thereby release the implant, is fully supported by the specification, including page 7, lines 18 through 20, which describe extension of grabber 160 from actuator assembly 126 to expand and release the implant.

Claim 1 also has been amended to include the limitation that the retaining element directs the grabber toward a closed position, whereby the grabber is substantially contained within the outer sleeve when the trigger is released. Support for this amendment can be found at page 7, lines 20 through 22, which states:

When trigger mechanism 120 is released, grabber 160 recedes into actuator assembly 126 and compresses, thereby engaging the implant or returning to its normally closed position.

No new matter has been added.

#### Election of Species

The Examiner stated that claims 8-11, 14 and 16-30 are withdrawn from further consideration pursuant to 37 C.F.R. §1.142(b) as being drawn to a non-elected species, there being no allowable generic or linking claim.

Applicants agree with the Examiner's assessment as applied to claims 8, 10, 14 and 16-30. However, claims 9 and 11 are fully supported by Figure 2A, which represents the species elected for prosecution. Specifically, claim 9 is dependent from claim 7 and includes the limitation that grabber tips include a first pair of slots for engaging a first engagement tab of the implant and a second pair of slots for engaging a second engagement tab of the implant. The first and second pair of slots are described at page 7, lines 28-29 as items 162a and 162b, respectively and are shown in Figure 2A. Item 162a represent the first pair of slots and item 162b represent the second pair of slots. As described with reference to Figure 6a, first pair of slots 162a engages an engagement tab 712 on an artificial disc 330 (which is also shown in Figure 4 that was also elected as a species by Applicants' representative Joseph Maraia, as indicated by the Examiner). A second pair of slots, 162b would engage engagement tab 722 (labeled in Figure 4). Support for this arrangement is set forth at page 10, lines 11 through 17:

In one embodiment, the user aligns grabber 160 (Fig. 2A) of implantation instrument 100 with alignment slot 323 on implant clip 300. Once aligned, the user squeezes trigger mechanism 120 (Fig. 1) on implantation as joint 100, thereby causing grabber tips 162a, 162b to be inserted over engagement tabs 712, 722, on artificial disc 330 (Figure 4). Once grabber tips 162 are inserted

over engagement tabs 712, 722, the user releases trigger mechanism 120, causing grabber tips 162 to engage engagement tabs 712, 722 on artificial disc 330 as shown in Fig. 5.

Therefore, claim 9 is fully supported by the elected species represented by Figure 2A and Figure 4.

Similarly, claim 11, which depends from claim 9, also is supported by Figure 2A. Specifically, claim 11 includes the additional limitation of a sizing slot located between the first pair of slots and the second pair of slots to allow for a variation of tab and slot dimensional differences. The sizing slot is represented as item 166 in Figure 2A, as described at page 8, lines 9 through 11:

Figs. 2A-2C show grabber 160 in the expanded position. Each grabber 160 also includes sizing slot 166 to allow for a variation of tab and grabber slot dimensional differences.

Applicants respectfully request reconsideration of withdrawal of claims 9 and 11.

#### Rejection of Claims 1-7, 12 and 15 under 35 U.S.C. §102(b)

Claims 1-7, 12 and 15 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No.: 6,110,179, by Flivik, *et al.*, (hereinafter Flivik, *et al.*). Among other items, the Examiner stated that Flivik, *et al.*, teach a grabber that includes grabber tips for mechanically engaging an implant (Figure 23) and that the grabber is capable of being removably coupled at 267 to the inner shaft.

Flivik, *et al.*, teach a prothesis inserter that employs, in one embodiment, and as represented by the Examiner with reference to Figure 23, clip 262 (identified by the Examiner as a “grabber”). As described in Flivik *et al.*, at column 13, lines 7-8, clip 262 is “pushed over” boss 260 of attachment element 230. Attachment element 230 is also shown in Figure 20, and is described at column 12, lines 16 through 42, as one of a two-part construction that also includes plate 234. Plate 234, as stated at column 13, lines 7 through 13, connects to clip 262 by “the squeezing effects of the rails 235 on the ends of the supports 263” to thereby “clip the supports in a desired position on the boss 260, the effect [sic] of the compression on the supports acting as a clamp.” The resulting assembly is similar to the one piece assembly shown in Figure 17 which,

when employed to insert a prosthesis, as represented in Figure 16, is attached to body component 201 by tapered socket 210, which also appears in Figure 20. As described at column 11, lines 31 through 36, with reference to Figure 16, additional tapered socket 211 fits over the tapered spigot 212 of the femoral prosthesis 207. Tapered socket 211 also appears in Figure 23, which was referenced by the Examiner. Insertion of the prosthesis is described at column 11, lines 31 through 36 as follows:

The tapered socket 210 allows limited entry of the main body component 201 while allowing full passage of the operating rod 204. The attachment element 209 also has an additional tapered socket 211 which fits over the tapered spigot 212 of the femoral prosthesis 207 to cooperate therewith and to firmly locate thereon.

Column 12, lines 5 through 15 further describe insertion of the femoral prosthesis:

To release the femoral prosthesis 207, the pivotal lever 203 is rotated about the pivotal 214 which causes one end of the lever to bear upon the distal end of the operating rod. This causes the spring 205 to be compressed allowing the operating rod 204 to travel within the tubular main body component 201. The shaped end 206 of the operating rod 204 is now caused to bear upon the femoral prosthesis 207 to release the tubular main body component 201 from the attachment element 209 and allowing the attachment 209 to be released from the tapered spigot 212 of the femoral prosthesis 207.

The embodiment shown in Figures 20-23 operates in the same manner as described with reference to Figure 16. Therefore, as represented, main body component 201 is described as engaging only tapered socket 210.

Therefore, attachment element 230 is engaged at clip 262 by serrations 265. Rails 235 (Fig. 20) engage ridges 268 (Fig. 23) of clip 262 and element 230 engages main body component 201 (identified by the Examiner as outer sleeve 201) at tapered socket 210. Clip 262 is pushed over boss 260 and rim 261 of attachment element 230 engages serrations 265. A femoral prosthesis 207, resting within the two-part construction shown in Figure 20 is inserted by action of pivotal lever 203 which, as described above, causes shaped end 206 to bear upon femoral prosthesis 207 to thereby release "tubular main body component 201 from the attachment element

209 and [allow] the attachment 209 to be released from tapered spigot 212 of femoral prosthesis 207.”

There is no disclosure or suggestion in Flivik, *et al.* of a retaining element, such as item 205, which the Examiner identified as a retaining spring, wherein the retaining element directs a grabber, identified by the Examiner as item 262, toward a closed position, as does Applicants’ claimed implant device. Specifically, there is no disclosure suggestion that clip 262 is removably coupled to inner shaft 204 at 267 or anywhere else on clip 262.

Further, there is no disclosure suggestion in Flivik, *et al.*, that actuation of a trigger, such as pivotal lever 203, will extend a grabber, such as clip 262, from within an outer sleeve, such as tubular main body component 201, to thereby release an implant. Nor is there any disclosure or suggestion in Flivik, *et al.*, that a retaining element, such as spring 205, will direct a grabber such as clip 262, to a closed position, whereby the grabber is substantially contained within the outer sleeve, identified by the Examiner as main body component 201, when the trigger is released.

Therefore, Flivik, *et al.*, do not disclose or suggest Applicants’ claimed implantation device, as set forth in amended claim 1. Claims 2-7, 9, 11-13 and 15 depend from independent claim 1. Therefore, there also is no disclosure or suggestion in Flivik, *et al.*, of the subject matter of these claims. Reconsideration of the withdrawal of this rejection is respectfully requested.

Rejection of Claims 1-7, 12-13 and 15 under 35 U.S.C. §102(e)

Claims 1-7, 12-13 and 15 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No.: US 2005/0055031 A1, by Lim (hereinafter “Lim”). In particular, the Examiner stated that Lim teaches a frame having a trigger mechanism, 60, an outer sleeve 128 and 178, mechanically coupled to the frame, an inner shaft, 130 and 134, having a grabber 122 and 124, for mechanically engaging an implant, where in the inner shaft is slidably disposed within the outer sleeve, and a retaining spring element, 214, for directing the grabber toward a closed position, and specifically referenced Figures 1, 2 and 11.

Lim teaches devices and methods for inserting spinal implant, and, as shown in Figure 11, and described at page 5, paragraph 63, includes lever arms 130, 134 between upper plate 128 and bottom plate 178 (collectively referenced by the Examiner as an outer sleeve). Lever arms 130, 134 are linked to clamping members 122, 124 (collectively referenced by the Examiner as

“the grabber”). As described at paragraph 63, application of force to lock release button 240 compresses lock spring 214 (referenced by the Examiner as “retaining spring element” 214) to thereby disengage locking arms 202, 204 from lever arms 130, 134. As further stated at paragraph 63, when disengaged, “lever arms 130, 134 can be pivoted away from longitudinal axis 23[shown in Figure 2], thus moving clamping members 122, 124 away from one another.”

There is no disclosure or suggestion in Lim that items 130, 134 (referenced by the Examiner as an “inner shaft”) is slidably disposed along a major axis of the inner shaft within the outer sleeve, as set forth in Applicants’ amended claim 1. Rather, movement of lever arms 130, 134 are identified as moving toward or away from longitudinal axis 23, which would be transverse to the major axis of arms 130 and 134. Further, there is no disclosure or suggestion in Lim that actuation of second handle member 60, identified by the Examiner as a “trigger,” extends clamping member 122, 124 (identified by the Examiner as a “grabber”), from the upper and lower plates 122, 124 (identified by the Examiner as an “outer sleeve”), to thereby release an implant, as in Applicants’ claimed device. Further, there is no disclosure or suggestion that lock spring 214 (identified by the Examiner as a “retaining spring element”) directs a grabber towards a closed position, whereby the grabber is substantially contained within the outer sleeve when the trigger is released. Even in the event that the “trigger” were identified as item 242, instead of item 60, there is no disclosure that release of the trigger causes the grabber to be substantially contained within the outer sleeve when the trigger is released.

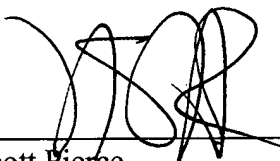
Therefore, as with Flivik, *et al.*, there is no disclosure or suggestion of the Applicants’ claimed implant device, as set forth in amended claim 1. Claims 2-7, 9, 11-13 and 15 depend from independent claim 1 and the subject matter of these claims also is not disclosed or suggested by the teachings of Lim.

Summary and Conclusion

Claim 1 has been amended to include additional limitations fully supported by the specification. Applicants respectfully request reconsideration of withdrawal from consideration of claims 9 and 11, which are clearly set forth in elected species represented by Figure 2A, as described in the specification. Neither Flivik, *et al.* nor Lim, either separately or in combination, disclose or suggest Applicants' claimed implant device, as set forth in amended claim 1. Therefore, independent claim 1 and dependent claims 2-7, 9, 11-13 and 15 meet the requirements of 35 U.S.C. §102(b) and 102(e). Reconsideration and withdrawal of the outstanding rejections are respectfully requested.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

N. Scott Pierce

Registration No. 34,900

Telephone: (978) 341-0036

Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: 6/05/06